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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,406	11/18/2005	Tomasz Troczynski	U008 0632/GSO	4838

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EXAMINER

AL-AWADI, DANAH J

ART UNIT	PAPER NUMBER
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1615

NOTIFICATION DATE	DELIVERY MODE
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06/28/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/527,406	Applicant(s) TROCZYNSKI ET AL.	
	Examiner DANAH AL-AWADI	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-9,11-13 and 37-43 is/are pending in the application.
- 4a) Of the above claim(s) 39-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-9,11-13,37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3 pages 06/07/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Applicant's amendments and remarks filed 11/05/2009. The Examiner acknowledges the following:

Claims 6 10, 14-16, and 45-59 are cancelled.

Thus, claims 1-5, 7-9, 11-13, 37 and 38 currently represent all pending claims under examination.

Information Disclosure Statement

Information Disclosure Statement (IDS) submitted on 06/07/2010 is acknowledged and has been reviewed.

WITHDRAWN REJECTIONS

Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

NEW REJECTIONS

The following rejections are newly added based on Applicant's amendments/remarks:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 -4 are rejected under 35 U.S.C. 102(b) as being anticipated by Trogolo et al. US 6,436, 422.

Trogolo et al. US 6,436, 422 (hereafter the '422 patent) teaches hydroxyapatite coatings on stents with thickness from about 0.5um to about 100 um (abstract, claim 2, line 30 column 3, line 51 column 5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1,2, 3-4,7, 9, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gao et al. US 6,113,993 and Pacetti et al. 2002/0123801.

Regarding claims 1, 2, 3-4, 7-9, 12, and 13 Gao et al. (hereafter the '993 publication) teach coating metal substrates with a calcium phosphate compound. The coated substrate is used as an implant, and more preferably a titanium implant. (abstract) The calcium phosphate compound includes tricalcium phosphate, hydroxyapatite, and combinations thereof. (abstract) The coatings can include antibiotic, antimicrobials or proteins. (abstract) The '993 publication teach that present methods in the art for making calcium phosphate coatings or hydroxyapatite coatings result in porous coatings that can consist of less than a micron in thickness. (column 2, line 40-41) The '993 publication teach coating thickness include from 0.1 micron to 20 micron. (column 3 lines 58-60) Regarding the percentage of coating as recited in claim 7, the '993 publication teach in figures 2B and 2C that the coating on the surface of the substrates can vary as a matter of design choice, where half the substrate can be covered with a calcium phosphate particle layer or all of the substrate can be covered with a calcium phosphate particle layer. Furthermore, it would have been within the purview of the skilled artisan to optimize the coating as MPEP 2144.05 recites " where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine optimization."

The '993 publication does not expressly teach wherein the implant is a stent or that the drug inhibits restenosis.

Pacetti et al. (hereafter the '801 publication) teach implantable medical devices such as stents which contain a first composition coating of particles. The particles comprise hydroxyapatite or calcium phosphate. (see claim 1, claim 7, claim 5). The '801 publication teaches porous coatings (paragraph [0080])and also teaches including antirestenosis agents as the

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active agent (paragraph [0057]) . Nevertheless, it is well known in the art for implants to have a coating comprising a drug for inhibiting restenosis, as taught by the '801 publication. It would have been obvious to one of ordinary skill in the art to include a drug for inhibiting restenosis in order to improve the treatment for restenosis. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to formulate the coatings taught by the '993 publication onto stents because the '801 publication exemplifies that it is well known in the art to form coatings of hydroxyapatite or calcium phosphate on stents. It would have been prima facie obvious to one of ordinary skill in the art to design the coatings of the '993 publication to include drugs that inhibit restenosis particularly in view of the '801 publication which exemplifies that drugs used to inhibit restenosis are advantageous to use with stents and may be contained within the pores of hydroxyapatite coatings.(Claims 1, 5, see paragraph 0057, 0070 0080, 0095 and example 23). There would have been a reasonable expectation of success as the '993 publication and the '801 publication teach porous coatings.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to include the coatings taught by the '993 publication onto stents because the '801 publication exemplifies that it was well known in the art to form coatings of hydroxyapatite or calcium phosphate on stents.

Claims 5, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Geo et al. 6,113,993 and Pacetti 2002/0123801 with respect to claim 1 as presented above, further in view of Choi et al. 2000.

The combined teachings of the '993 publication and the '801 publication teach a stent with calcium phosphate coating less than 1 micron in thickness.

Neither the '993 publication or the '801 publication teach tensile bond strength, the percentage of the coating.

Choi et al. teach calcium phosphate layers of metal implants (abstract and the introduction of page 469). The calcium phosphate layer was formed on a titanium based metal substrate. Choi et al. further teaches a hydroxyapatite layer formed on the surface of a Ti-based alloy (paragraph 4 of the introduction page 469). Choi et al. also teaches forming a tricalcium phosphate coating (paragraph 1 of the results and discussion page 470). With regards to the thickness of the calcium phosphate coating, Choi et al. teach that the coating layers started out with a thickness of 700nm (0.7um) (paragraph 1 of the results and discussion page 470). It would have been within the purview of the skilled artisan optimize the coating thickness as a matter of design choice to create different release profiles. (see MPEP 2144.05) With regards to the tensile bond strength, Choi et al. teach that the ion-beam method does not require heat treatment to get a good bond strength and decreased dissolution rate (Fig. 6 and the last paragraph of page 471). Figure 4 teaches bond strengths of greater than about 40MPa.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Choi et al. with the modified teaching of the '993 publication and the '801 publication to formulate a stent composed of ceramic material such as calcium phosphate and hydroxyapatite that have a tensile strength greater than 20 MPa. Choi et al. teaches that by employing the ion-beam assistance technique, a hydroxyapatite coating layer that has a high bond strength and at the same time a low dissolution rate can be deposited

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on a metal substrate (the last paragraph of page 471). This is advantageous because if the dissolution rate is faster than implants stabilization, the coating would be useless (second paragraph of the introduction on page 469). One would have been motivated to make the tensile bond strengths of the modified '993 publication and '801 publication higher than 40 MPa because Choi et al. further teaches that if the bond strength of a coating layer with the metal substrate is weak, the layer may become separated from the implant during applications in the human body and the detached fragments would have adverse effects on the implant or tissue surrounding it (second paragraph of the introduction on page 469).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gao et al. US 6,113,993 and Pacetti et al. 2002/0123801 as applied to claims 1,2, 3-4,7, 9, 12, and 13 above, and further in view of Falotico et al. PGPUB 2001/0029351.

With regards to claim 11, the limitations have been discussed supra. The combination of the '993 and the '801 publication do not disclose two coating layers where a drug is present in each coating, however Falotico et al. PGPUB 2001/0029351 (hereafter the '351 publication) teaches an implant (stent) having two coatings where a drug is present in each coating (Figs 3-5). It would have been obvious to one of ordinary skill in the art to utilize two calcium phosphate coatings with a drug in each coating in order to create to provide the most efficacious treatment for post-angioplasty restenosis [0032].

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gao et al. US 6,113,993 and Pacetti et al. 2002/0123801, as applied to 1,2, 3-4,7, 9, 12, and 13 above, and further in view of Teller et al. 5,759,376.

The '993 patent and the '801 publication have been discussed supra. The combination does not disclose a electrochemically deposited coating, however Teller et al. 5,759,376 (hereafter the '376 patent) discloses that it is well know in the art to apply calcium phosphate coatings via electrochemical deposition (abstract and the paragraph of line 5 column 1).

The '376 patent teaches electrochemical deposition of hydroxyapatite coating layers onto metal and ceramic surfaces (abstract). The '376 patent teaches that the advantages are that hydroxyapatite can be deposited on metal and ceramic surfaces of the type required for use as biocompatible implants in human and veterinary medicine. The '376 patent teaches multi-layer coatings of hydroxyapatite are contemplated (line 4, column 2). Furthermore, the '376 patent teaches that application of uniform, well adhering hydroxyapatite layers, containing a small proportion of amorphous materials having a thickness of optimum proportions, is assured by a sol-gel pretreatment (the paragraph of line 39 column 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to deposit a coating of hydroxyapatite via electrochemical deposition on a implant such as the stent. One would have been motivated to do so because the prior art teaches this is an advantageous method to apply coatings of hydroxyapatite on metal and ceramic surfaces and that uniform, well adhering hydroxyapatite layers having optimal thickness can be produced. It would have been obvious to one of ordinary skill in the art to apply the calcium

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phosphate layer via electrochemical deposition in order to produce uniform and thin calcium phosphate coatings, as desired.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danah Al-awadi whose telephone number is (571) 270-7668. The examiner can normally be reached on 9:00 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DA/

Examiner, Art Unit 1615

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

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